REMARKS

Applicants would like to thank the Examiner for the telephone interview on April 23, 2002, during which the Examiner's objecting to the sequence listing were discussed. As noted in the Examiner's Interview Summary, the Preliminary Amendment, Verified Statement and Sequence Listing (paper copy and electronic copy) filed by the applicants on October 10, 2001 were sufficient to comply with the sequence listing requirements. Thus, the Examiner's objections set out in paragraphs 16 through 19 of the Office Action have been obviated.

The Examiner objects to the disclosure of the present application, asserting that the "telomerase inhibitor II and telomerase inhibitor VII are identified as DNA sequences but are not also identified by sequence ID numbers." With regard to telomerase inhibitor II, Applicants note that the specification was amended by the Preliminary Amendment filed October 10, 2001 to refer to the nucleic acid sequence of telomerase inhibitor II as SEQ ID NO:3. Thus, contrary to the Examiner's assertion, the nucleic acid sequence of telomerase inhibitor II is identified by a sequence ID number.

With regard to telomerase inhibitor VII having a nucleic acid sequence of (5'-d(GGG~GGG)-3'), this sequence does not qualify as a nucleotide sequence as defined in 37 CFR §§ 1.821 through 1.825, and therefore does not require a sequence identification number. Specifically, 37 CFR § 1.821(a) provides that a "nucleotide... as used in §§ 1.821 through 1.825 [is] interpreted to mean... an unbranched sequence of ten or more nucleotides." This section further provides that the number of nucleotide bases in a sequence is determined based upon the number of specifically defined nucleotide bases, and does not include bases signified, e.g., by "n". Thus, the nucleic acid sequence of telomerase VII only has six specifically defined nucleotide bases, and therefore does not need to be included in the sequence listing or referenced by a sequence identification number.

In paragraph 21, the Examiner says the "title of the invention is not descriptive." Applicants disagree; the invention broadly relates to reducing hair growth and thus the title of the invention is "Reduction of Hair Growth." As a result, applicants have not amended the title.

The 35 U.S.C. § 112 rejection of claims 33, 37, and 40-43 have been addressed by amendment. Applicants request that the rejection be withdrawn.

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Applicants now will focus on the 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) rejections of claim 1 in view of Hirota, U.S. Pat. 4,923,862 ("Hirota").

Claim 1 relates to a method of reducing hair growth that includes two steps. The first step is essentially a diagnostic step and requires "selecting an area of skin on a mammal from which reduced hair growth is desired." The second step is "applying to said area of skin a dermatologically acceptable composition comprising an inhibitor of telomerase in an amount effective to reduce hair growth."

Hirota describes a composition including ofloxacin, which is an inhibitor of telomerase (see claim 2 in the present application). The compositions can be applied topically to treat skin diseases caused by microorganisms. See the Background of the Invention (col. 1, lines 10-28) and col. 6, lines 10-29 of Hirota.

Hirota does not disclose or suggest that the composition can be used to reduce hair growth. The Examiner glosses over this point by reasoning that "[t]he ability of a composition containing ofloxacin to reduce hair growth is inherent and is not given patentable weight over the prior art." (See page 10 of the office action.)

But claim 1 is not directed to a composition, but rather to a method of treating a specific condition (reduction in growth of undesired hair). Hirota does not expressly or inherently disclose or suggest the two steps required by claim 1, and as a result the 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) rejections based on Hirota should be withdrawn.

Applicants will address the 35 U.S.C. § 102(b) rejection first. To anticipate a claim under 35 U.S.C. § 102(b), a prior art reference must describe every feature of the claim, either expressly or inherently. See Tyler Refrigeration v. Kysor Industrial Corp., 227 U.S.P.Q. 845, 846-47 (Fed. Cir. 1985) ("each element of the claim... [must be] found in a prior art patent or publication, either expressly or under principles of inherency"). There is no dispute that Hirota fails to expressly describe, for example, "selecting an area of skin on a mammal from which reduced hair growth is desired." As a result, Hirota is not an express anticipation of claim 1.

Thus, Hirota cannot anticipate claim 1 unless a person of ordinary skill in the art in practicing the process taught by Hirota, inherently would also practice the processes covered by claim 1. This occurs only if that person necessarily would perform the claimed processes when performing the prior art processes. See Ex Parte Levy, 17 U.S.P.Q.2d 1461, 1464 (1990), where

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the Patent and Trademark Office Board of Patent Appeals and Interferences explained (emphasis in original):

> In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. In re King, 801 F.2d 1324, 231 U.S.P.Q. 136 (Fed. Cir. 1986); W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); In re Oelrich, 666 F.2d 578, 212 U.S.P.Q. 323 (CCPA 1981); In re Wilding, 535 F.2d 631, 190 U.S.P.Q. 59 (CCPA 1976); Hansgirg v. Kemmer, 102 F.2d 212, 40 U.S.P.Q. 665 (CCPA 1939).

Similarly, the Court of Customs and Appeals in In re Oelrich, 212 U.S.P.Q. 323, 326 (1981)[1] explained (emphasis original);

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

Hirota does not satisfy the standard described in Levy and Oelrich because a person of ordinary skill in the art, practicing the method described by Hirota, would not necessarily also practice the method covered by claim 1. For example, claim 1 requires selecting an area of skin on a mammal from which reduced hair growth is desired. An area of infected skin does not necessarily also have unwanted hair. Faced with similar facts, the Court of Custom and Patent Appeals in In re Marshall, 198 U.S.P.Q. 344, 346 (1978), reversed a 35 U.S.C. § 102 rejection, reasoning (emphasis added):

> [W]e must reverse the board's rejection of claims 1-4 under 35 U.S.C. § 102 since the primary reference, the PDR [the prior art reference], does not disclose every material element of the claimed subject matter. These claims are directed to a weight control process. Applicant uses an effective amount of the anesthetic, oxethazaine, to inhibit release of the pancreatic secretory hormones, secretin and pancreozymin, in order to control weight. The PDR, however, teaches using drugs containing the anesthetic oxethazaine to inhibit release of the acid-stimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. Nothing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone every lost weight by following the PDR

[1]Quoting Hansgirg v. Kemmer, 40 U.S.P.Q. 665, 667 (CCPA 1939).

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teachings it was an unrecognized accident. An accidental or unwilling duplication of an invention cannot constitute an anticipation.

Accordingly, claim 1 is not anticipated by Hirota.

Turning next to obviousness, a prior art reference cannot make a method covered by a claim obvious unless the prior art suggests practicing the method. Hirota does not satisfy this standard because Hirota is dealing with treating infection, not with reducing the growth of unwanted hair. Treating infections is unrelated to reducing hair growth. As a result, a person of ordinary skill in the art, reading Hirota, would be motivated to practice the method covered by claim 1. Therefore, the 35 U.S.C. § 103(a) rejection of claim 1 should be withdrawn.

The art rejections of the remaining (dependent) claims should be withdrawn for at least the same reasons the art rejection of claim 1 should be withdrawn.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a $110.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Tu Nguyen, Tu Nguyen Reg. No 42,934 for
Robert C. Nabinger
Reg. No. 33,431

Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

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Version with markings to show changes made

In the specification:

Paragraph beginning at page 2, line 20 has been amended as follows:

--In one aspect, the invention provides a method (typically a cosmetic method) of reducing unwanted mammalian (preferably human) hair growth, for example, androgen-stimulated hair growth, by applying to the skin an inhibitor of telomerase in an amount effective to reduce hair growth. The unwanted hair growth may be undesirable from a cosmetic standpoint or may result, for example, from a disease or an abnormal condition (e.g., hirsutism). In another aspect, the invention provides a method of reducing unwanted mammalian hair growth by applying to the skin a compound that reduces telomerase levels in hair follicles. In another aspect, the invention provides a method of reducing unwanted mammalian hair growth by applying to the skin a compound that reduces telomerase mRNA expression. In a further aspect, the invention provides a method of reducing unwanted mammalian hair growth by applying to the skin a compound that promotes the erosion of telomeric DNA.--

In the claims:

Claims 49-51 have been cancelled.

Claims 1, 33, and 40-43 have been amended as follows:

--1. (Amended) A method of reducing mammalian hair growth which comprises

selecting an area of skin on a mammal from which reduced hair growth is desired; and

applying to said area of skin a dermatologically acceptable composition comprising an inhibitor of telomerase in an amount effective to reduce hair growth.

33. (Amended) The method of claim 1, wherein the concentration of said inhibitor in said composition is between 0.1% and 30% by weight of the composition.

40. The method of claim [36] 37, wherein said area of skin is on a leg of the human.

41. (Amended) The method of claim [36] 37, wherein said area of skin is on an arm of the human.

42. (Amended) The method of claim [36] 37, wherein said area of skin is in an armpit of the human.

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43. (Amended) The method of claim [36] 37, wherein said area of skin is on the torso of the human.--

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